

**Application No.:** 10/754,919  
**Filing Date:** 01/10/2004

### REMARKS

Claims 1, 2, 4-21, 23-30, 32-38 and 40 remain pending, of which Claims 8-19 and 35 have been withdrawn from consideration. Claims 1, 20, 28, 29, 36 and 37 are amended and Claims 3, 22, and 31 are cancelled. No new claims are added. No new matter has been added.

The results of the Office Action mailed November 29, 2007 are summarized as follows:

CLAIM NOS.	DISPOSITION/REJECTION		
	BASIS	PRIMARY REFERENCE	SECONDARY REFERENCE(S)
1-4, 20-23, 27-29, 31, 33-37, 39	102(b)	Schroeder US 6,254,635	n/a
1-4, 28, 29, 33-37	102(e)	Devellian US 2005/0070952	n/a
5, 24, 30, 38	103(a)	Schroeder US 6,254,635	Duran US 5,489,297
5, 24, 29, 30, 33-36, 38	103(a)	Devellian US 2005/0070952	Duran US 5,489,297
1-4, 20-23, 27-29, 31, 33-37, 39	103(a)	Pavcnik US 2004/0186558	Schroeder US 6,254,635
1-4, 20-23, 27-29, 31, 33-37, 39	102(b)	DiMatteo US 6,440,164	n/a
1-4, 20-23, 27-29, 31, 33-37, 39	103(a)	DiMatteo US 6,440,164	Schroeder US 6,254,635
5, 24, 30, 38	103(a)	DiMatteo US 6,440,164	Schroeder US 6,254,635; Duran US 5,489,297
6, 7, 25, 26, 32, 40	103(a)	DiMatteo US 6,440,164	Schroeder US 6,254,635; Soetikno US 2002/0143387

#### Schroeder Reference - Claim 1

Schroeder does not disclose or suggest all of the limitations recited in Claim 1. For example, Schroeder does not teach or suggest "bio-absorbable means for (1) bidirectionally blocking blood flow past said stent" as recited in amended Claim 1.

Schroeder teaches a calcification-resistant heart valve utilizing an anti-calcific elemental metal, for example, a suture with a coating of anti-calcific elemental metal. Schroeder at 8:25-33 and 54-56. The heart valve is "configured to replace different natural valves." Schroeder at 8:28-30. The valves have three leaflets that open and close the valves to control the blood flow. Schroeder 8:42-46. Thus Schroeder teaches a one-way heart valve that functions in the same way as the natural valve which it is used to replace. Namely the valve opens and closes with the pumping action of the heart to allow blood to flow in only one direction.

Amended Claim 1 recites, among other things, “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent.” The heart valve taught by Schroeder does not bidirectionally block blood flow. Rather the heart valve “defines a blood flow path” through which blood flows routinely in one direction and the heart valve blocks blood flow in the other direction. Schroeder at 8:45-46. Schroeder therefore fails to teach at least “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent,” of amended Claim 1.

In addition, Schroeder fails to suggest “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent.” It would not be obvious to modify the heart valve of Schroeder to bidirectionally block blood flow because of the adverse consequences on the heart. Such a modification would stop blood flow through the heart thus causing a heart attack if the modified Schroeder valve were implanted in the heart. Such a modification would therefore frustrate the purpose of Schroeder of providing a long lasting one-way heart valve that opens and closes with the pumping of the heart.

For at least the reasons discussed above, the Schroeder reference does not disclose or suggest the limitations of amended Claim 1, including the limitation “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent.” In view of the foregoing, Applicants respectfully submit that the rejection of Claim 1 over Schroeder should be reconsidered and withdrawn.

#### Schroeder Reference - Other Independent Claims

Although they recite combinations of features that differ somewhat from that recited in amended Claim 1, the other independent claims rejected by the Examiner as anticipated by Schroeder are patentable at least for the same reasons provided above with respect to Claim 1. For example, amended independent Claim 20 recites “a wall that blocks blood flow bidirectionally past said stent body,” and amended Claims 29 and 37 recite respectively, a “blocking wall blocks blood flow bidirectionally through said stent body lumen” and a “closed configuration to block blood flow bidirectionally.” These limitations are not disclosed or suggested by the Schroeder reference.

In view of the foregoing, Applicants respectfully submit that the rejections of Claims 20, 29 and 37 over Schroeder should be reconsidered and withdrawn.

Devellian Reference - Claim 1

Devellian does not disclose or suggest all of the limitations recited in amended Claim 1. For example, amended Claim 1 requires a “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent when said means is implanted in a vein and in a closed configuration, and (2) permitting blood flow through said stent when said means is implanted in a vein and in an open configuration, . . . wherein the cross-sectional size of said stent body at said bio-absorbable means is the same when said means is in the open configuration and when said means is in the closed configuration.” This is not taught by Devellian.

Devellian teaches a device to be inserted into the left atrial appendage (“LAA”) so as to “reduce the likelihood of thrombus formation therein.” Devellian at ABSTRACT. The Devellian device remodels the surface of the LAA by providing a smooth surface, the liner or sock, that reduces the volume of the LAA. Devellian at [0011] and [0029]. In addition to the liner, the Devellian device may also have an anchor which “maintains the liner at its intended delivery site and seals the device to the LAA periphery.” Devellian at [0035]. Devellian teaches that the anchor is expanded to help maintain the device at its intended delivery site. Devellian at [0036]-[0037], see also [0038] and [0040]. In the preferred embodiment, the anchor component is self-expandable and also expands the liner upon deployment. Devellian at [0036]. Once the device is properly in place, vascular flow within the LAA is promoted and the possibility of thrombus formation is reduced. Devellian at ABSTRACT and [0013].

The Examiner in rejecting Claim 1 over Devellian asserts that the anchor is the equivalent to the “bioabsorbable stent” of the above-referenced application and that the liner is the equivalent of the “bioabsorbable closure”. Office Action at 2.

Devellian does not anticipate a “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent when said means is implanted in a vein and in a closed configuration, and (2) permitting blood flow through said stent when said means is implanted in a vein and in an open configuration, . . . wherein the cross-sectional size of said stent body at said bio-absorbable means is the same when said means is in the open configuration and when said means is in the closed configuration” as required by amended Claim 1. As discussed above, when deployed the device of Devellian has only one state. In this state blood does not flow past the

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device through the LAA. Of course, blood does continue to pass through the heart which one may argue is past the device but such flow is not through the Devellian device. Devellian does not anticipate Claim 1 because the claim requires a closed configuration and an open configuration, where at best Devellian has only one configuration when deployed. Devellian does not have a closed configuration and an open configuration when deployed.

In view of the foregoing, Applicants respectfully submit that the rejection of Claim 1 over Devellian should be reconsidered and withdrawn.

#### Devellian Reference - Other Independent Claims

Although they recite combinations of features that differ somewhat from that recited in amended Claim 1, the other independent claims rejected by the Examiner as anticipated by or obvious over Devellian are patentable for the same reasons provided above with respect to Claim 1. For example, amended independent Claim 29 requires “said blocking wall being adjustable and having an open configuration in which said blocking wall permits blood flow through said stent body lumen, and a blocking configuration in which said blocking wall blocks blood flow bidirectionally through said stent body lumen” and Claim 37 requires “an adjustable bio-absorbable blocking wall coupled with the side wall and configurable from an open configuration to a closed configuration to block blood flow bidirectionally and to a degree sufficient to induce clotting and fibrosis at an implantation site of the body.” At least these limitations are not disclosed or suggested by the Devellian reference.

In view of the foregoing, Applicants respectfully submit that the rejections of Claims 29 and 37 over Devellian should be reconsidered and withdrawn. Devellian does not teach or suggest all of the recited limitations of Claims 29 and 37 and Devellian therefore does not anticipate Claims 29 and 37. In addition, Claim 29, rejected as obvious over Devellian in view of Duran, is believed to be allowable as the cited references, even if combined, do not collectively teach or suggest all of the claimed limitations.

#### Pavcnik Reference - Claim 1

Pavcnik does not disclose or suggest all of the limitations recited in Claim 1. For example, Pavcnik does not teach or suggest a “bio-absorbable means for (1) bidirectionally

blocking blood flow past said stent when said means is implanted in a vein and in a closed configuration, and (2) permitting blood flow through said stent when said means is implanted in a vein and in an open configuration” as recited in amended Claim 1.

Pavcnik teaches a single-leaflet valve, an occluder and a multi-leaf valve. Pavcnik at [0084]. All three devices function differently but are based on a similar frame. *Id.* The single-leaflet and multi-leaf valves are similar in function to the valve disclosed in Schroeder and discussed above:

the device 10 can act as an artificial valve 43 such as the type used to correct valvular incompetence. . . . [I]n the open configuration . . . , the partial covering 58 has been displaced toward the vessel wall 70 due to positive fluid pressure or flow in a first direction 46, e.g., normal venous blood flow, thereby opening a passageway 65 through the frame 11 and the lumen 34 of the vessel 33. As the muscles relax, producing flow in a second, opposite direction . . . , the partial covering 58 acts as a normal valve by catching the backward flowing blood and closing the lumen 34 of the vessel. Pavcnik at [0095].

Thus the valves of Pavcnik are one-way valves and do not bidirectionally block blood flow.

Pavcnik also discloses an occluder, “to occlude a duct or vessel, close a shunt, repair a defect, or other application where complete or substantially complete prevention of flow is desired.” Pavcnik at [0096]. The occluder only has a closed configuration that “once deployed, is capable of almost immediately occluding an artery.” Pavcnik at [0018]. *See also* Pavcnik at [0096]. Thus the occluder of Pavcnik does not have an open configuration “permitting blood flow past said stent” as required by amended Claim 1.

The teachings of Pavcnik do not disclose how the one-way valves and occluder could be combined, nor would it be obvious to do so. Pavcnik discloses a frame that can be used for different purposes such as one-way valves and occluders but Pavcnik does not teach combining these purposes to get one device that satisfies all of the limitations of amended Claim 1. Therefore, Pavcnik does not teach or disclose a device that has a “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent when said means is implanted in a vein and in a closed configuration, and (2) permitting blood flow through said stent when said means is implanted in a vein and in an open configuration” as recited in amended Claim 1.

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As explained previously, Schroeder suffers from similar deficiencies as Pavcnik. Therefore Pavcnik in view of Schroeder does not does not disclose or suggest the limitations of amended Claim 1. In view of the foregoing, Applicants respectfully submit that the rejection of Claim 1 over Pavcnik in view of Schroeder should be reconsidered and withdrawn.

Pavcnik Reference - Other Independent Claims

Although they recite combinations of features that differ somewhat from that recited in amended Claim 1, the other independent claims rejected by the Examiner as obvious over Pavcnik in view of Schroeder are patentable for the same reasons provided above with respect to Claim 1. For Example amended independent Claim 20 recites “an adjustable bio-absorbable closure device associated with said stent body, said adjustable bio-absorbable closure device comprising: an open configuration in which said bio-absorbable closure device permits blood flow through said stent body while implanted in a vein; and a blocking configuration in which said bio-absorbable closure device forms a wall that blocks blood flow bidirectionally past said stent body while implanted in a vein.” Amended independent Claim 29 requires “said blocking wall being adjustable and having an open configuration in which said blocking wall permits blood flow through said stent body lumen, and a blocking configuration in which said blocking wall blocks blood flow bidirectionally through said stent body lumen” and 37 requires “an adjustable bio-absorbable blocking wall coupled with the side wall and configurable from an open configuration to a closed configuration to block blood flow bidirectionally and to a degree sufficient to induce clotting and fibrosis at an implantation site of the body.” These limitations are not disclosed or suggested by Pavcnik in view of Schroeder.

In view of the foregoing, Applicants respectfully submit that the rejections of Claims 20, 29 and 37 as obvious over Pavcnik in view of Schroeder, are believed to be allowable as the cited references, even if combined, do not collectively teach or suggest all of the claimed limitations.

DiMatteo Reference - Claim 1

DiMatteo does not teach or suggest all of the limitations recited in Claim 1. For example, DiMatteo does not teach or suggest a “bio-absorbable means for (1) bidirectionally blocking

blood flow past said stent when said means is in a closed configuration, and (2) permitting blood flow past said stent when said means is in an open configuration” as recited in amended Claim 1.

DiMatteo teaches a device with two portions: leaf frames and a non-absorbable cell covering that blocks blood flow in one direction in a lumen. The device of DiMatteo is similar to the multi-leaf valve of Pavcnik. DiMatteo describes the functioning of the valve in this way:

The leaf valve portion desirably includes a number of valve leafs which are deflected between the closed and open configurations when the fluid pressure differential thereacross exceeds a predetermined threshold. That is, the fluid pressure differential acts to open the valve when the fluid pressure upstream of the valve leaf portion is greater than the fluid pressure downstream of the valve leaf portion. DiMatteo at 3:18-25.

Thus, like Pavcnik, the DiMatteo device is a one-way valve that does not bidirectionally block blood flow, but rather opens and closes with the flow of fluid through the valve. For this reason, DiMatteo does not anticipate Claim 1.

As explained previously, Schroeder suffers from similar deficiencies as DiMatteo. Therefore DiMatteo in view of Schroeder does not disclose or suggest a device with a “bio-absorbable means for (1) bidirectionally blocking blood flow past said stent when said means is in a closed configuration, and (2) permitting blood flow past said stent when said means is in an open configuration” as stated in amended Claim 1. In view of the foregoing, Applicants respectfully submit that the rejections of Claim 1 over DiMatteo and over DiMatteo in view of Schroeder should be reconsidered and withdrawn.

#### DiMatteo Reference - Other Independent Claims

Although they recite combinations of features that differ somewhat from that recited in amended Claim 1, the other independent claims rejected by the Examiner as anticipated by DiMatteo or in the alternative, as obvious over DiMatteo in view of Schroeder are patentable for the same reasons provided above with respect to Claim 1.

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### Dependent Claims

Numerous dependent claims remain pending but rejected over the prior art. Applicant respectfully submits that the pending dependent claims are also in condition for allowance, due to their dependence from allowable based claims as well as their recitation of further novel and non-obvious combinations of features.

In addition to the arguments herein, Applicants maintain that the arguments made in previous responses dated February 26, 2007 and November 11, 2007 are still valid in regard to the previously cited references, in so far as the claims have not been amended to remove these arguments.

### Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although the present communication may include alterations to the claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including any subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history should not infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application. Moreover, any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.



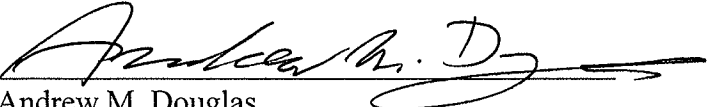
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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